IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RICKY BOWLING and BRITTANY BOWLING, Plaintiffs, vs. JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CO., AND MITSUBISHI TANABE PHARMA CORP., Defendants.	CIVIL ACTION NO.: 3:16-cv-02048-BRM-LHG CIVIL ACTION (Document Filed Electronically) **Return Date: September 6, 2016**

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT JANSSEN PHARMACEUTICALS, INC. & JOHNSON & JOHNSON, CO.'S MOTION TO DISMISS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

State Cases

State Statutes

Federal Rules

Federal Regulations

Other Authorities

I. INTRODUCTION

Invokana is a name-brand medication prescribed for the treatment of Type 2 diabetes. Plaintiff Ricky Bowling developed ketoacidosis due to ingestion of Invokana As a result, he asserts 13 claims against Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson ("J&J"), and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi")". His wife asserts derivative loss of consortium claims. Janssen and J&J ("Defendants") have moved to dismiss Plaintiffs' complaint. His wife asserts derivative loss of consortium claims. The Court should deny Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

First, Defendants put the Rule 8 plausibility standard on a pedestal equal to that of a claim sounding in fraud under 9(b). As a result of that unfounded supposition, together with a circumscribed reading of Plaintiffs' complaint, Defendants cobble together case law to seek dismissal, citing to numerous (off-point) medical *device* cases or *generic* pharmaceutical cases in defense of this *brand-name* pharmaceutical drug suit. As medical devices and generic drugs are subject to different rules than brand-named prescription medications, the cases cited by Defendants are inapplicable here. Applying the correct Rule 8 plausibility standard with on-point case law nets an entirely different result: his claims survive under both New Jersey and Kentucky law.[1] Mr. Bowling is entitled to punitive damages under either New Jersey or Kentucky law.

Second, Mr. Bowling' design defect-based claims (Counts 2 and 5–7) are not preempted by federal law. Defendants again cherry-pick from limited case law supporting their sweeping contention that all design defect cases against generic **and brand-name** prescription drug manufacturers would be preempted despite binding Supreme Court precedent to the contrary.

Third, Defendants assert that claims against Johnson & Johnson are preempted because Johnson & Johnson is merely a "holding company" and had no authority to amend the design or labeling for Invokana. This is inaccurate. As demonstrated by judicially-notable materials

[1] This court need not, at this juncture reach a choice of law analysis because Plaintiffs' claims survive under both states' laws. To the extent that the Court may ultimately believe that any of Plaintiffs' claims fail under either states' laws, that is a question for another day. *See* Section III, *infra*.

publicly available from both the FDA and Johnson & Johnson's own website, J&J actively manages Janssen Pharmaceuticals and even shares research and marketing personnel with Janssen. It was and remains intimately involved in the development and labeling of Invokana. Thus, Plaintiffs' claims against Johnson & Johnson are not preempted.

II. BACKGROUND

Mr. Bowling began using Invokana to treat diabetes in 2015 and subsequently experienced ketoacidosis. *See* Compl. ¶¶ 4, 8, 28. Plaintiffs allege that Defendants failed to adequately warn of the risk of ketoacidosis from ingesting Invokana, along with other injuries that can be caused by the drug, some of which may also result to ketoacidosis.

But Plaintiffs allege more than the mere use of Invokana in connection with Mr. Bowling's injuries. Plaintiffs allege that Defendants knew the mechanism of action of the sodium-glucose cotransporter 2 inhibitors and that Invokana's mechanism of action results in ketoacidosis, as well as other injuries. *Id*. ¶¶ 18-22. Moreover, Defendants were aware of a growing number of Invokana adverse event reports yet did not change the label, or otherwise warn physicians, patients, or the public at large of those dangers. *Id.* ¶¶ 23-28, 34-37, 39.

III. CHOICE OF LAW

On a motion to dismiss for failure to state a claim, a "defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In order for Defendants to successfully dispose of ***any*** of Plaintiffs' claims, Defendants bear the burden on showing that his claims fail under **both** Kentucky and New Jersey law in their opening brief. Stated another way, because Defendants have failed to make any claim-by-claim arguments required for a choice-of-law analysis -- let alone any discussion of conflict at the outset -- Defendants bear the burden of proving the claims fail under **both** of the set-forth states (Kentucky and New Jersey) for each claim.

In any event, choice of law issues are inappropriate to resolve on a motion to dismiss in the first instance when key factual matters have yet to develop. *See, e.g., Argabright v. Rheem Mfg. Co.*, No. CV 15-5243 (JBS/AMD), 2016 WL 3536621, at *4 (D.N.J. June 28, 2016)

(denying a motion to dismiss and simultaneously finding that "the factual record is not full enough to make a choice of law determination, the Court will postpone the choice of law analysis to a later stage"); *Krys v. Aaron*, 106 F. Supp. 3d 472, 481 (D.N.J. 2015) (stating that "the factual inquiry necessary for a choice of law analysis often proves 'inappropriate or impossible' at the motion to dismiss stage 'when little or no discovery has taken place.'" (quoting *Erlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 700-01 (D.N.J. 2011) (citation omitted) (also citing additional cases that have determined that a choice-of-law analysis is premature at the motion to dismiss stage); *Snyder v. Farnam Co.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (same); *Harper v. LG Elecs. USA, Inc.*, 595 F. Supp. 2d 486, 491 (D.N.J. 2009) (same).

IV. LEGAL STANDARD

A plaintiff's pleading requires "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. at 570). To meet the plausibility standard, a plaintiff's allegations must show that defendant's liability is more than "a sheer possibility." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

"The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* All a Plaintiff must show are facts that tend to "'raise a right to relief above the speculative level[.]'" *Siwulec v. J.M. Adjustment Servs., LLC*, 465 F. App'x 200, 202 (3d Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, (2007)). "The issue before the Court is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." *Touristic Enters. Co. v. Trane, Inc.*, No. CIVA 09-02732 (SRC), 2009 WL 3818087, at *1 (D.N.J. Nov. 13, 2009) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)); *see also Phillips v. Cnty. of Allegheny*, 515 F. 3d 224, 234 (3d Cir. 2008) (relying on *Twombly* to hold that to survive a motion to dismiss a complaint must assert "enough facts to raise a reasonable

expectation [] discovery will reveal evidence of the necessary element").

The Third Circuit observed, applying *Twombly* and *Iqbal*, that in evaluating the legal sufficiency of a complaint's allegations, a court "accept[s] all factual allegations as true, construe[s] the complaint in the light most favorable to the plaintiff, and determine[s] whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips*, 515 F. 3d at 233 (quoting *Pinker v. Roche Holdings Ltd.*, 292 F. 3d 361, 374 n.7 (3d Cir. 2002)). "The Court's role is not to determine whether the non-moving party 'will ultimately prevail' but whether that party is 'entitled to offer evidence to support the claims.' *Williams v. Hospice*, No. CV-16-2095-JLL-JAD, 2016 WL 4149987, at *3 (D.N.J. Aug. 3, 2016) (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011)).

The Court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64. Moreover, "[i]n deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of the public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (emphasis added).

Additionally, F.R.C.P. Rule 15(a) declares that leave to amend "shall be freely given when justice so requires." "[I]f a complaint is subject to a Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile." *Phillips*, 515 F.3d at 245 (citing *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004)).

As developed below, the Complaint states allegations that give rise to a plausible, not merely possible, entitlement to relief. Plaintiffs' allegations are not threadbare recitals of the elements of a cause of action but instead, provide more than sufficient detail for the Defendants to have notice of the claims against them.

V. ARGUMENT

A. Mr. Bowling's Claims are Sufficiently Pled under Both Kentucky and New Jersey Law

1. Plaintiffs Specify the Extent and Roles of Each Defendant's Wrongdoing

Janssen, as a wholly owned subsidiary of J&J, "marketed, advertised, distributed, and sold" Invokana in addition to "researching, developing, designing, licensing, manufacturing, [and] supplying" it. Compl. ¶¶ 9, 15. J&J too was directly involved in such "researching, developing, designing, licensing, manufacturing, distributing, supplying, selling[,] marketing, and introducing [of Invokana] into interstate commerce." *Id.* ¶10.

Defendants, however, aver to this Court that J&J is a mere "holding company and did not design, manufacture or sell Invokana." Def. Mot. at 5. Defendants artfully avoid Plaintiffs' other allegations (which this Court must accept as true)—that J&J also partook in the "researching … developing, and introducing [of Invokana] into interstate commerce." Compl. ¶ 10. Defendants do not dispute these roles, nor can they.

Defendants emphasize the fact that Janssen is the company that manufactures Invokana in Puerto Rico. Publicly-available documents, judicially noticeable by this Court,[2] accessed from

[2] For the same reasons that Defendants cite that this Court make take judicial notice of FDA documents, this court may do the same of the FDA documents cited herein. *See* Def. Mot. at 5, n.6; *see also Horne v. Novartis Pharms. Corp*., 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("The Court may take judicial notice of and consider the public record of the FDA . . . .").

Similarly, the Defendants' own website may be judicially noticed. *See O'Toole v. Northrop Grumman Corp*., 499 F.3d 1218 (10th Cir. 2007) (holding that the district court had abused its discretion in refusing to take judicial notice of information from the defendant's website under Rule 201); *see also Hendrickson v. eBay, Inc*., 165 F. Supp. 2d 1082, 1084 (C.D. Cal. 2001) (same); *Under a Foot Plant, Co. v. Exterior Design, Inc.*, No. 6:14-cv-01371-AA, 2015 WL 1401697, at *2 (D. Or. Mar. 24, 2015) (taking judicial notice of an archived version of the defendant's website).

The Court may accept the facts contained on Defendants' own website for the truth of the matter asserted therein. "For purposes of a 12(b)(6) motion to dismiss, a court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Doron Precision Sys., Inc. v. FAAC, Inc*., 423 F. Supp. 2d 173, 179 n.8 (S.D.N.Y. 2006); *accord Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015) (taking judicial notice of printouts of the defendant's own website because defendant did "not actually dispute the factual material reflected in [them]," but rather "simply . . . prefer[red] that the Court not consider [them]").

FDA and on J&J's own website, verifies J&J's involvement in the labeling, product launch, and marketing of Invokana. Thus, even absent further discovery, based on the following, there is no question that J&J was involved in the product alleged to cause Mr. Bowling's injuries.

J&J posted an online article entitled "Behind the Product Labels."[3] The article details how a third-party label manufacturer is **"**a true partner ***for Johnson & Johnson"*** because the label manufacturer produced Invokana bottle labels in anticipation of FDA approval yet stood at the ready over the Easter holiday to change the label—at ***J&J's*** direction—in the event of "a potential request from the FDA for changes to the label." *Id.* J&J's Director of Trade Accounts is quoted as the person "who manages the relationship between [the third-party label manufacturer] **and Johnson and Johnson** and [who] over saw the product [Invokana's] launch."[4]

J&J's own website also posted (and continues to host) a "Media Fact Sheet" about Invokana, detailing in more generic terms understandable to the public at large about the drug's mechanism of action.[5]

Moreover, even though J&J attempts to establish itself as a mere holding company through its financial filings (*see* Def. Mot. at n. 5), other financial filings on J&J's own website further point to the importance of Invokana to J&J's bottom line. For example, J&J's 2012 Annual report exclaimed that "**We [J&J]** have an exciting and late-stage pipeline of differentiated medicines. New Drug Applications are presently under review in the United States and in the European Union seeking approval for INVOKANA* (canagliflozin), **our [J&J's]** first pharmaceutical treatment for patients with type 2 diabetes."[6] Thus, to the extent J&J attempts to shield itself from liability, by creating a set of nested Russian dolls, J&J is nevertheless at the top of the stack and directly

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[3] Exhibit A, Behind the Product Labels, *available at:* https://www.jnj.com/sites/default/files/pdf/JJ%20Diversity%20--%20National%20Label%20and%20Cardinal%20--%2012-23-14.pdf .
[4] *Id* (emphasis added).
[5] Exhibit B, Media Fact Sheet, *available at*: https://www.jnj.com/sites/default/files/pdf/Janssen_INVOKANA%20FactSheet.pdf .
[6] Exhibit C, J&J's 2012 Annual Report at 7, *available at* https://www.jnj.com/sites/default/files/pdf/JNJ2012annualreport.pdf (emphasis added).

involved, understandably, in the affairs of its underlings.[7] To wit, J&J's 2015 Annual Report states that:

> The **Executive Committee of Johnson & Johnson is the principal management group** responsible for the strategic operations and allocation of the resources of the Company. This Committee **oversees and coordinates the activities of the Company's three business segments**: Consumer, **Pharmaceutical** and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies.[8]

J&J describes Invokana as one of the products in its Pharmaceutical segment in its 2015 Annual Report.[9]

Indeed, J&J was involved with Invokana from its initial NDA application. Administrative documents & correspondence for the drug approval package for Invokana establishes J&J's role in the submission of Invokana for the FDA's approval.[10] As part of the NDA application, all FDA investigators had to reveal any financial conflicts of interest. For Invokana, a minimum of thirteen FDA investigators received (and were forced to disclose) various consulting fees ***from J&J*** (not Janssen).[11]

Moreover, Brandon Porter is listed as the Associate Director, Regulatory Affairs, for Janssen Research & Development on the NDA-related correspondence. Brandon Porter, however, wears two hats. He was simultaneously (and remains to be) the Associate Director of Global Regulatory Affairs *for J&J* and, while at J&J, was a "[m]ember of the canagliflozin regulatory

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[7] Exhibit D, *see* 2015 First Quarter Report of Drug Quarter-over-Quarter sales, *available at* http://www.jnj.com/sites/default/files/pdf/Johnson-Johnson-First-Quarter-2015-Financial-Charts.pdf (listing Invokana).
[8] Exhibit E, J&J 2015 Annual Report, *available at* http://files.shareholder.com/downloads/JNJ/1709744668x0x881109/474857DD-8E67-43B1-BB38-0A9712D93545/2015_annual_report_.pdf, at 1 (emphasis added).
[9] *Id.* at 2.
[10] All FDA drug approval package documents are *available at*: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000TOC.cfm.
[11] Exhibit F, FDA Medical Reviews at 23, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000MedR.pdf.

team that gained FDA approval of Invokana."[12] Similarly, Leslie Schaefer, a consumer brand director at *J&J*, is the director of marketing for Invokana.[13]

In sum, Janssen and J&J are not haphazardly 'lumped together.' Johnson & Johnson has a special role on the development and marketing of Invokana in its supervision of Janssen's business.[14] *See BK Trucking Co. v. PACCAR, Inc.*, No. CV 15-2282 (JBS/AMD), 2016 WL 3566723, at *6 (D.N.J. June 30, 2016) (naming defendants together in one action was allowed because "Plaintiffs have alleged that all defects requiring repair [when the specific] component systems is uniquely within Defendants' control. The Court cannot expect Plaintiffs to provide more specificity about the [component] without the benefit of discovery.").

2. Mr. Bowling's claims are plausibly pled under Kentucky law

As explained below, Mr. Bowling's claims are plausibly pled under Kentucky law. In all products liability cases under Kentucky law, regardless of the theory, a plaintiff must prove that the product was defective. *Leslie v. Cincinnati Sub–Zero Products, Inc*., 961 S.W.2d 799, 803–04 (Ky.App .1998). Thus, "the question is whether the product creates such a risk of an accident of the general nature of the one in question that an ordinarily prudent company engaged in the manufacture of such a product would not have put it on the market." *Montgomery Elevator Co. v. McCullough*, 676 S.W.2d 776, 780 (Ky.1984).

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[12] Exhibit G, FDA Administrative Documents & Correspondence at 88, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000Admincorres.pdf; *see also* Exhibit H, LinkedIn, Brandon Porter, *available at:* https://www.linkedin.com/in/brandon-porter-3aa46a.

[13] Exhibit I, LinkedIn, Leslie Schaefer, *available at:* https://www.linkedin.com/in/leslieschaefer66bb744.

[14] For example, many of the top leadership of J&J wear two hats and sit on leadership team of Janssen as well. As a few examples, Joaquin Duato is the Executive Vice President and Worldwide Chairman, Pharmaceuticals for Johnson & Johnson, but also is listed as part of Janssen's leadership. *See* "Our Leadership, Janssen", *available at* http://www.janssen.com/about/our-leadership. The same is true for Paul Stoffels, Chief Scientific Officer, Johnson & Johnson and Worldwide Chairman, Pharmaceuticals; Dr. William Hait, Global Head, Research & Development;
Patrick Verheyen, Global Head of Business Development; and Linda Fedow, Global Lead, Pharmaceuticals Communication & Public Affairs. *Id.*

Mr. Bowling has satisfied these preliminary elements for every form of his product liability claims (manufacturing defect, failure to warn, and design defect). *First*, he was injured. Compl. ¶4 ("Plaintiff RICKY BOWLING developed diabetic ketoacidosis."). *Second*, Plaintiffs pled that Invokana is unreasonably dangerous. *See* Compl. ¶¶19-24 (explaining the increased dangers of SGLT2 diabetes drugs over non-SGLT2 drugs—including and especially Invokana—in light of mounting FDA adverse event reports). *Third*, the, if Defendants had been prudent, they would not have put Invokana on the market in the first place, knowing of its inherent risks. Compl. ¶¶78-79.

a. Manufacturing Defect (Count 1)

In addition to the preliminary product liability elements discussed above, "[u]nder Kentucky law, a manufacturing defect exists when a product leaves the hands of the manufacturer in a defective condition because it was not manufactured or assembled in accordance with its specifications." *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 835 (W.D. Ky. 2014) (citing *Gentry v. Gen.Motors Corp.*, 2006 WL 1382293, at *1 (W.D.Ky. May 15, 2006)). The result is that "a defendant is held strictly liable if the plaintiff proves the product was in a defective condition unreasonably dangerous to the user or consumer [upon receipt]." *Montgomery Elevator Co. v. McCullough ex rel. McCullough*, 676 S.W.2d 776, 780 (Ky.1984). "Unreasonably dangerous" means "a product that is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Greene v. B.F. Goodrich Avionics Systems, Inc.*, 409 F.3d 784, 789 (6th Cir.2005) (quoting Restatement (Second) of Torts §402A cmt. i). "Defective" means "that the product does not meet the reasonable expectations of the ordinary consumer as to its safety." *Id.* (quoting *Worldwide Equip., Inc. v. Mullins*, 11 S.W.3d 50, 55 (Ky.Ct.App.1999)).

Mr. Bowling has satisfied these elements. First, he alleges that the Invokana pills he received were defective when they left the hands of the Defendants. Compl. ¶¶46(a)-(b), (d), 47. The Invokana pills lacked the characteristics of other (correctly-manufactured) Invokana pills, and hence made them unreasonably dangerous. Compl. ¶¶46(c), 47. Hence, the Invokana pills did not meet Mr. Bowling's expectations – or any reasonable consumer's expectations – because of the

severe safety side-effects it caused to him. Compl. ¶47.

Other courts have allowed such claims to proceed to discovery (post-*Twombly-Iqbal*) to establish such a claim in Kentucky. For example, in *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, a manufacturing defect claim regarding an implantable heart-lead defibrillator device. There, as here, the plaintiffs averred that the device "possess[es] a manufacturing defect because the actual manufacture of those leads deviated from the specifications." *Id.* at 833; *see also* Compl. ¶46(c) (containing a vitually identical allegation).

Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims, like this one (subject to "plausibility"). Plaintiffs need not show, at this stage, "how" J&J and Janssen's manufacturing defect caused his injuries and "how" the Invokana pills consumed by Mr. Bowling were different than its intended design. Def Mot. at 7. To require such facts at this stage would be akin to requiring an expert report filed with the complaint. No holding has ever gone so far.

b. Design Defect (Count 2)

In addition to the preliminary product liability elements discussed above, "[a] plaintiff in Kentucky can bring a defective design claim under either a theory of negligence or strict liability. The foundation of both theories is that the product is 'unreasonably dangerous' ... So under either theory, it is the legal duty of the manufacturer to use reasonable care to protect against foreseeable dangers. In a design defect case courts use some form of risk-utility analysis to assess the decisions made by manufacturers with respect to the design of their products." *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky.2003). This risk-utility analysis balances the available alternative designs with the risk of the chosen design. *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky.2004).

And is often the case in complex medical and pharmaceutical cases, "[e]xpert testimony may be required in [such] cases in which the question is of a complex and technical nature such that a lay juror could not, without the aid of the expert, infer that a defective condition of the product caused the product's failure and caused the injury to the plaintiff." *Stevens v. Keller*

Ladders, 1 F. App'x 452, 458 (6th Cir. 2001). Ultimately, however, it is "**issue for the jury** under Kentucky products liability law." *Id.* at 462.

Again, Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims. Plaintiffs need not support their complaint with expert testimony as to complicated matters – matters reserved for an expert, at this stage of the litigation. According to Defendants, Plaintiffs must present – in their complaint – an expert report on how SGLT2 inhibitors, and Invokana specifically, increase the risk of ketoacidosis. It is unclear how such a presentation would be done absent an expert report. So long as the litigation proceeds and Plaintiffs' expert's theory is viable, it is the trier of fact who is to decide whether J&J and Janssen's design was reasonable under a risk-utility balancing test. Plaintiffs need to prove their case in the complaint.

c. Failure-to-Warn (Count 3)

Plaintiffs' failure to warn claim is simple: Mr. Bowling suffered diabetic ketoacidosis. Compl. ¶4. Plaintiffs claim that J&J and Janssen failed to warn about the risks of developing diabetic ketoacidosis. Compl. ¶54. There is no disconnect between the failure to warn claim and the injuries Mr. Bowling suffered as Defendants contend. Def. Mot. at 10-11.

Defendants' make the specious argument that, despite the fact that Plaintiffs alleged that Defendants "knew or should have known" about a risk of diabetic ketoacidosis, Plaintiffs have no "facts" to back-up this allegation. Compl. ¶34. But the facts are simple: by way of judicially noticeable May 2016 label change – a warning that Defendants fail to acknowledge in their brief, the FDA required Defendants to *strengthen* the warnings for Invokana.

Specifically, the FDA requested new precautions under two of the six safety labeling sections for Invokana.[15] Among those changes was an added section under "WARNINGS AND PRECAUTIONS" for "Ketoacidosis," including "**postmarketing reports**, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and

[15] *See* Exhibit K, FDA May 2016, Drug Safety Labeling Changes, *available at*: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm505586.htm.

institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis."[16] The same revised warnings included the fact that doctors "should be assessed for ketoacidosis [for patients presenting with ketoacidosis-like symptoms] regardless of presenting blood glucose levels, as ketoacidosis associated with INVOKANA may be present even if blood glucose levels are [at otherwise normal levels]." *Id.*

The warnings in effect at the time of Mr. Bowling's consumption instead contained ***no*** warning whatsoever of Ketoacidosis.[17]

In any event, the fact that Defendants' only serious support for the dismissal of Plaintiffs' failure-to-warn claim is to quibble about the strength (or lack thereof) of the 2013-version of the warnings versus the present warnings speaks volumes. These are questions of fact for a jury, not to be resolved as a matter of law on a motion to dismiss.

a. Warranty Claims (Counts 4, 5, and 7)

1. Express Warranty

Though Defendants rightly points to Ky. Rev. Stat. Ann. § 355.2-313 as the applicable UCC section on express warranty, they, again, delete pertinent text in order to make their case for dismissal more compelling. An express warranty is formed under Kentucky law when there is "**[a]ny** affirmation of fact or promise made by the seller to the buyer which **relates to the goods** and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." *Id.* at § 355.2-313(1)(a) (emphasis added). An express warranty remains even if no "formal words such as 'warrant' or 'guarantee'" are used. *Id.* at § 36–2–313(2).

Here, it is undisputed (or, at a minimum, plausibly alleged in the complaint or through

[16] *See* Exhibit L, FDA Invokana warning changes over Time, *available at:* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm400577.htm (emphasis added).
[17] *Compare* Exhibit J, 2013 Invokana warnings, *available at* http://www.accessdata.fda.gov/drugsatfda_dsssocs/label/2013/204042s000lbl.pdf *to* Exhibit O, Revised May 2016 Invokana Warnings, *available at:* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf (adding ketoacidosis warnings for the first time).

judicially-noticeable facts discussed above) that: 1) Invokana was safe and fit for its intended purposes through Defendant's statements as of Mr. Bowling's ingestion,[18] and 2) that the description of Invokana was not safe because it has serious side effects, namely the one suffered by Mr. Bowling: diabetic ketoacidosis.[19]

Though, "[a]s a general rule, Kentucky law requires a plaintiff to be in privity of contract with a defendant to maintain a breach of warranty claim," Ky. Rev. Stat. Ann. § 355.2-318 creates an exception whereby "intended beneficiaries of [a defendant's] express warranties" are also subject to express warranty liability. *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 738 (W.D. Ky. 2013). For example, in *Levin v. Trex Co., Inc*., 2012 WL 7832713 (W.D.Ky. Mar. 5, 2012), the defendant offered an express warranty in writing and through advertisements to consumers. There, the court, citing similar cases from other jurisdictions, stated that a plaintiff may maintain an implied warranty claim against a manufacturer when a plaintiff is a third party beneficiary of a contract between the manufacturer, defendant, and a third party when the third part is the intended beneficiary of the product. *See also Williams v. Volvo–White*, 2003 WL 22681457, at *3 (Ky.App. Nov. 14, 2003) (coming to this same conclusion); *Gooch v. E.I. Du Pont de Nemours & Co.*, 40 F.Supp.2d 863 (W.D.Ky.1999) (not discussing the privity requirement, but applying Kentucky law and allowing an express warranty action by a consumer against a manufacturer where no buyer-seller relationship existed but the consumer relied on warranties that were made by the manufacturer on the product's label).

Here, there is no doubt who the Defendants intended to be the beneficiary of their product, through extensive web and other advertisements: patients – like plaintiff. The mere fact that an intermediary prescribing doctor and dispensing pharmacist stand in the way of direct privity does not work as an escape hatch from liability to make false and incomplete promises of efficacy

[18] Compl. ¶66; *see also* Exhibit P, Defendants' Invokana website as of June 13, 2014, *available at* https://web.archive.org/web/20140613010318/http://www.invokana.com/about-invokana/what-is-invokana (stating that "It's the first of a new kind of prescription medicine that's proven to significantly lower blood sugar (A1C)", but containing ***no*** warnings under "IMPORTANT SAFETY INFORMATION" as to ketoacidosis).

[19] *See id.*; *see also* Compl. ¶67.

without recourse for plaintiff.

2. Implied Warranty

Defendants' sole argument for dismissal of the implied warranty claim is for lack of privity. But for the reasons discussed immediately above with respect to express warranties, the privity requirement should be relaxed in pharmaceutical cases – like this one – where the disconnect between plaintiff and the Defendants is through no fault of his own. In short, the intermediary prescribing doctor and pharmacist exist through a mechanism that is through no fault of plaintiff. *See Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d at 739 (W.D. Ky. 2013) (citing *In re Sony Vaio Comp. Notebook Trackpad Litig.*, 2010 WL 4262191, at *3 (S.D.Cal. Oct. 28, 2010) (holding that despite the rule requiring privity in a warranty action, "a plaintiff may maintain an implied warranty claim against a manufacturer when a plaintiff is a third party beneficiary of a contract between the manufacturer, [defendant], and a third party")).

b. Negligence-based Claims (Counts 6 and 9)

Defendants merely argue that because Plaintiffs' product-liability-based claims must fail (Count 1 [Manufacturing Defect], 2 [Design Defect], and 3 [Failure-to-Warn]), their negligence-based claims (Counts 6 & 9) must fail too. For the same reasons discussed above, those claims are plausibly pled and survive.

c. Fraud-based claims (Counts 8–11)

Defendants do not contest Plaintiffs' causation or losses allegations. Instead, Defendants only claim that Plaintiffs' "who, what, when, where, and why" claims are insufficient. Def. Mot. at 15. Defendants' chief complaint is that Plaintiffs failed to point to – among thousands of such examples – marketing materials about Invokana contained material facts about safety. Def. Mot. at 15, n. 17. But the court may consider all of the materials that Plaintiffs have already pointed to as judicially noticeable for this reason – for the same reason that Defendants have pointed to their external materials for consideration. *See* Section V.A.1. Each one of those (specifically-dated) statements made by each of the Defendants (or in concert) list who made them, and how they made them (in which medium). *See id.* The why is simple: "sales and profits at the expense of the health

and safety of the public." Compl. ¶173.

For example, Defendants' 2013 label, attached as Exhibit J, omits material safety information about Invokana. Fraud by omission is by its very nature difficult to plead with particularity. "Fraud by omission is not the same, at law, as fraud by misrepresentation, and has substantially different elements." *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747 (Ky. 2011). And Defendants' duty to disclose the harmful side effects of Invokana is triggered when there is either a partial disclosure of facts, *Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc.*, 113 S.W.3d 636, 641 (Ky. Ct. App. 2003), or "where one party to a contract has superior knowledge and is relied upon to disclose same." *Smith v. GMC*, 979 S.W.2d 127, 129 (Ky. Ct. App. 1998). Here, Defendants are clearly the party with the superior knowledge about the risks and side effects of Invokana, and hence owed a duty to disclose all of its side effects in the 2013 label.

Who:	Janssen and J&J
What:	Defendants "omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public." Compl. ¶138(b). Namely, nowhere in 2013 label do the Defendants disclose the risks of diabetic ketoacidosis ***at all***. It was not until the 2016 label that Defendants disclosed any such risks. Ex. O.
When:	March 2013 (date on page 41 of Ex. J)
Where:	In product boxes, disseminated to treating doctors and to the public at large.
How:	By prescribing doctors and public at large as to the relative safety of Invokana when compared to other similar diabetic medications. *See also* Compl. ¶¶116, 120-123, 137. 150.
Why:	"[S]ales and profits at the expense of the health and safety of the public." Compl. ¶173.

3. There is No Basis for Striking any of Plaintiffs' New Jersey Claims

a. It is too early to determine if Plaintiffs' implied warranty, negligence-based, and fraud-based claims (Counts 5–11) are subsumed by the New Jersey Product Liability Act

Although the Court may determine that certain claims are subsumed by the NJPLA at a later time, it is premature to make this determination at this phase absent a choice of law analysis. Defendants have made no meaningful effort to do so and Plaintiffs agree that on a motion to

dismiss, it is inappropriate to do so. [20]

b. The manufacturing defect (Count 1) is plausibly pled

Under New Jersey law, a manufacturing defect is a deviation "from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." *Myrlak v. Port Authority of N.Y. and N.J.*, 157 N.J. 84, 96 (1999) (quoting N.J.S.A. 2A:58C–2a). It occurs when the "product comes off the production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing specifications." As discussed, *see* Section V.A.2.a, Plaintiffs have so alleged. Compl. ¶¶46-47.

Importantly, "[t]he Supreme Court of New Jersey has held that the plaintiff may show the [manufacturing] defect through expert testimony or circumstantial evidence." *Ebenhoech v. Koppers Indus., Inc.*, 239 F. Supp. 2d 455, 472 (D.N.J. 2002) (citing *Myrlak*, 157 N.J. at 97). In such a scenario, "proof of proper use, handling, or operation of the product and the nature of the malfunction, may be enough to satisfy the requirement that something was wrong with it. Further, a defective condition can also be proven by the testimony of an expert." *Ebenhoech v. Koppers* Indus., Inc., 239 F. Supp. 2d 455, 472 (D.N.J. 2002). But Defendants' handling and packaging of Invokana is necessarily only in the knowledge of the defendants that discovery will reveal. Thus it is appropriate to withhold dismissal of this claim under New Jersey law given the broad scope of a manufacturing defect claim's proof.[21]

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[20] *See* Section III (discussing that is premature to make a finding on a choice of law on a motion to dismiss); *see also ADP, LLC v. Bakshi*, No. CV 15-8385 (CCC), 2016 WL 1223557, at *6 (D.N.J. Mar. 29, 2016) ("[D]isputes require discovery and further exploration before a proper choice of law analysis can be performed.")

[21] Moreover, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under Kentucky law. Thus, for the same reasons as stated above, Plaintiffs need not prove their case in their complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was manufactured at this stage of the litigation. All they must do is allege facts that make it plausible that it is the case. They have done so for the same reasons stated in Section V.A.2.a., *supra*.

c. The design defect (Count 2) is plausibly pled

Defendants insist that plaintiffs must show a reasonable alternative design and "facts" to support that a reasonable alternative design is feasible. Under New Jersey law,

> "[a] plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm. Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible."

Schraeder v. Demilec (USA) LLC, No. CIV. 12-6074 FSH, 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013) (citing *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570–71 (NJ 1998)).

These elements of proof at trial, however, are not required to be proven at the pleading stage. An alternative design need not be pled because "it is not required that the Plaintiffs always plead a reasonable alternative design." *Id.* "A plaintiff must prove ***either*** that the product's risks outweighed its utility ***or*** that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Am. Cyanamid Co.*, 155 N.J. at 570–71 (emphasis in the original). Thus, it is almost always that "the jury [i]s required to perform a risk-utility analysis." *Lewis v. Am. Cyanamid Co*., 155 N.J. at 560. And a jury's evaluation of of the risk-utility factors "may justify a conclusion that ***even though there is presently no alternative design*** which would make a product safer [liability may still be found]." *Smith v. Keller Ladder Co*., 275 N.J. Super. 280, 283-84 (N.J. App. Div. 1994) (emphasis added).

Even though not required under New Jersey law, as discussed, *see* Section V.A.2.b., *supra*, Plaintiffs have pointed to such a feasible alternative design: the existence of "alternative safer products" when compared against Invokana, which is "more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes." Comp. ¶¶25, 51(b), (c).[22]

[22] Again, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under Kentucky law. Thus, for the same reasons as stated above, Plaintiffs need not prove their case in their complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was designed at this stage of the litigation. All they must do is allege facts that make it plausible that it is the case. They have done so for the same reasons stated in Section V.A.2.b., *supra*.

But it is not only the existence of safer, alternative type 2 diabetes medications that form the basis for a design defect, it is also the insufficient and inadequately tested and labeled Invokana. Comp. ¶¶51(d), & (f). Defendants do not attempt to refute these allegations.

d. The failure to warn claim (Count 3) is plausibly pled

As noted at Section V.A.2.c., *supra*, weighing the adequacy of Defendants' warnings is not appropriate on a motion to dismiss. This is equally as true under New Jersey law as Kentucky law. See *In re Ductile Iron Pipe Fittings ("DIPF") Direct Purchaser Antitrust Litig.*, No. CIV. 12-711, 2014 WL 3971620, at *6 (D.N.J. Aug. 13, 2014) ("In ruling on a motion to dismiss, the Court may not weigh evidence or otherwise decide which version of the facts is true.") (citing *Acevedo v. Monsignor Donovan High Sch.*, 420 F.Supp.2d 337, 342 (D.N.J.2006).) Countless New Jersey Courts have held the same in the context of pharmaceutical cases. *See, e.g., In re Reglan Litig.*, No. A-2014-13T4, 2014 WL 5840281, at *7 (N.J. Super. Ct. App. Div. Nov. 12, 2014), *leave to appeal granted*, 224 N.J. 278, 132 A.3d 422 (App. Div. 2015); *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 197, 36 A.3d 541, 556 (N.J. 2012). Thus, for the same reasons stated in Section V.A.2.c., *supra*, this Court should not dismiss Plaintiffs' failure to warn claim.

e. Mr. Bowling's express warranty claim (Count 4) is plausibly pled

Defendants argue that plaintiffs failed to provide a pre-suit notice under New Jersey law of his express warranty claim. But because it is premature to determine if Plaintiffs' express warranty claim should be analyzed under Kentucky or New Jersey law (and because Defendants have made no attempt, as is their burden, to argue which should apply) the question of pre-suit notice under New Jersey Law (if even applicable) is premature. *See* Section III.

Defendants' remaining quarrels with Plaintiffs' express warranty claim are the same as those outlined as to the Kentucky claim: they want "more." But for the same reasons that Plaintiffs' express warranty claim would survive under Kentucky law, it survives under New Jersey law. *See* Section V.A.2.d.1.

4. Mr. Bowling's Claim for Punitive Damages (Count 12) Survives

Generally, New Jersey allows for punitive damages in cases where "the product

manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's [FDA's] regulations, which information was material and relevant to the harm in question." N.J. Stat. Ann. § 2A:58C-5c. As Defendants point out, however, following *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but, importantly, before *Wyeth v. Levine*, 555 U.S. 555, the New Jersey appellate decision held that punitive damages could not be sought under the facts of *McDarby v. Merck & Co*., 949 A.2d 223, 275–76 (N.J. Super. Ct. App. Div. 2008). *Wyeth* held that federal law does not preempt state torts claims imposing liability on drug labeling that the FDA had previously approved because FDA's "changes being effected" (CBE) regulation permits unilateral labeling changes that improve drug safety. 555 U.S. at 568 (citing 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). As such, the Supreme Court stated, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." 555 U.S. 555, 570–71. Thus, subsequent to *Wyeth*, this District and other districts across the nation have called *McDarby's* reasoning into question. "The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth*." *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009). "The holding of *McDarby*, however, has been called into doubt by *Wyeth* … and *Forman v. Novartis Pharmaceuticals Corp*., 793 F.Supp.2d 598 (E.D.N.Y. 2011)" *Hill v. Novartis Pharm. Corp.*, No. 1:06-CV-00939-AWI, 2012 WL 967577, at *2 n.2 (E.D. Cal. Mar. 21, 2012) (same).

Timing is critical. Because *McDarby* preceded *Wyeth*, the *McDarby* court did not have the ability to consider the Supreme Court's determination that a drug manufacturer may change the label of brand-name drugs without prior FDA approval for reasons of safety. Thus, it is possible for a drug manufacturer to come to know of information that would call for an updated warning (i.e., knowingly withhold information from the FDA), but fail to update the labeling, thereby satisfying N.J. Stat. Ann. § 2A:58C-5c.

With respect to Kentucky, Defendants only quarrel that punitive damages are a remedy, not a cause of action. But they have not stated, at all, why Plaintiffs should not be able to pursue such punitive damage as a matter of law given that Plaintiffs *have* included punitive damages in

their prayer for relief. Compl. p. 40. Thus, any determination on punitive damages under Kentucky law is premature because Plaintiff have done exactly what Defendants demand: prayed for such relief. In any event, such a question is one for a jury under Kentucky law – state statute requires as much: "If the trier of fact determines that punitive damages should be awarded, the trier of fact shall then assess the sum of punitive damages." Ky. Rev. Stat. § 411.186 (2).

B. Mr. Bowling's Design Defect-Based Claims Are Not Preempted By Federal Law

Invokana is a brand-name prescription drug for which there is currently no generic equivalent. Generally speaking, brand-name prescription drugs are regulated differently than generic prescription drugs. This is because it is the brand-name manufacturer that seeks approval from the FDA to market the drug and which is in possession of clinical testing data and safety information, conducted and collected both before and after a drug comes to market. By contrast, generic manufacturers do not generally conduct safety testing. Rather they are merely copying an existing formulation for a brand name drug. Indeed, that is why generic manufacturers must conform their product labels with those of the brand name manufacturers. 57 Fed.Reg. 17961 (1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval"). Courts have recognized this distinction and have generally ruled that state claims for failure to warn (and in some cases, design defect) against *generic* manufacturers are preempted. *See, e.g., In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012), *aff'd sub nom. In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) (dismissing all generic propoxyphene cases in a MDL). Courts, however, have not typically extended this protection to brand name prescription drug manufacturers.

Despite the Supreme Court precedent recognizing this distinction, Defendants argue that their *brand*-name drug should still be protected from liability under a theory of *conflict* preemption theory because it is the FDA, not the Defendants, that approved its drug design,

composition, and dosage. Def. Mot. at 21-27. While that may be true, it is the Defendants that submitted their drug for approval in the first instance. It is the Defendants that initially designed and developed Invokana, and submitted proposed labeling for the drug. Therein lies Defendants liability. Further, absent discovery regarding the regulatory submissions made by Defendants, as well as any communications between Defendants and the FDA, it is not what information was provided to the FDA regarding the safety of the drug. Thus, as a practical matter, any consideration of conflict preemption would be premature.

Nevertheless, Defendants cite to three Supreme Court cases that they claim require dismissal with prejudice. None of the three Supreme Court cases Defendants cite, as discussed below, at issue are on point, and certainly none of them mandate dismissal of Plaintiffs' claims.

First, *Wyeth* held that a brand-name drug manufacturer can be held liable for failure to warn claims because regulations allow a manufacturer to implement label changes with the FDA's prior approval. Thus, the Court stated:

> Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case. . . . We conclude that it is not impossible for Wyeth to comply with its state-and federal-law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.

Wyeth v. Levine, 555 U.S. 555, 581 (2009).

The second case cited by Defendants, the *Mensing* case, reiterates *Wyeth* but instead does preempt failure-to-warn claims when a ***generic***, and not brand-name, drug is at issue.

> We recognize that from the perspective of [plaintiffs] Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, *substituted generic metoclopramide* instead, federal law pre-empts these lawsuits.

PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011) (emphasis added). The Plaintiff in this case took brand name Invokana, not a generic substitute—because no such generic drug exists. Compl.

¶8.

Finally, the third case cited by the Defendants, *Bartlett*, simply extended *Mensing* such that claims involving ***generic*** drugs applies to design-defect claims (and not only failure to warn claims as were at issue in *Mensing*). "As *PLIVA* made clear, federal law prevents *generic drug manufacturers* from changing their labels." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) (emphasis added). Thus, these cases provide no basis for dismissal of a brand-name drug.

The Defendants cite several lower court decisions in jurisdictions not binding on this Court that extend the *Mensing* and *Bartlett* opinions beyond the realm of generic drugs—but mostly applying preemption *outside the context of pharmaceutical drugs*. Def. Mot. at 24-25.

For example, Defendants cite to the Third Circuit case *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680 (3d Cir. 2016). That citation is odd for multiple reasons. First, *Sikkelee* held that the Federal Aviation Act of 1994 (hardly a pharmaceutical case) does *not* act to preempt state-law based aircraft product liability claims. *Id.* at *683. The Third Circuit so held because of the "presumption against preemption [under which] Congress must express its clear and manifest intent to preempt an entire field of state law." *Id.* Second, the Third Circuit expressly states the opposite of the proposition for which Defendants say it stands for.

> In a series of recent preemption cases, the [Supreme] Court has **distinguished between brand-name drugs and their generic equivalents**, determining that at least some state law tort claims may be brought against brand-name drug companies because such companies have the ability to make some unilateral changes to their labels without additional regulatory preapproval, but such claims against generic drug manufacturers cannot survive a conflict preemption analysis because the generic manufacturers are bound by federal law to directly mimic their brand-name counterparts.

Id. at *703 (emphasis added).

As the Third Circuit boiled down so well, generic drug claims of all types usually fail, but branded-name drugs (like Invokana) are not preempted. Two sister courts in this Circuit agree, of course. "The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs. I conclude that its preemption cases do not extend to the manufacturers of these products." *Brown v. Johnson & Johnson*, 64 F.Supp.3d 717, 721 (E.D. Pa. 2014).

> [T]he same federal regulations that apply to generic manufacturers do not necessarily apply to brand-name manufacturers, such as the defendants. … This explains why the failure-to-warn claim brought against a generic drug manufacturer in PLIVA was preempted but failure-to-warn claim brought against the brand-name manufacturer in *Wyeth v. Levine* was not. … Following from this logic, I find that *Bartlett*—a case involving a generic manufacturer and following *PLIVA v. Messing*—does not apply to the plaintiff's design defect claim against a brand-name manufacturer. Under the dictates of *Wyeth v. Levine*, preemption is not warranted.

Terry v. McNeil-PPC, Inc., (In re Tylenol (Acetaminophen) Mktg.), No. 2436, 2015 WL 7075949, at *21–22 (E.D. Pa. Nov. 13, 2015).

The outlier cases cited by Defendants cannot be reconciled with the explicit language in *Mensing* and *Bartlett* and should be disregarded by the Court. As one district court noted about the rationale espoused by Defendants by the outside-of-this-circuit cases they cite, "[i]f this is the correct interpretation of *Bartlett*, then it appears virtually all design defect cases against generic and brand-name prescription drug manufacturers alike would be preempted." *Trahan v. Sandoz, Inc*., No. 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015). Defendants' interpretation of the law of federal preemption cannot be (and is not) correct.

C. All of Mr. Bowling's Claims against Johnson & Johnson Remain Valid

As noted above, *see Section* V.A.1., *supra*, Johnson & Johnson had direct involvement in the development, sale, and marketing of Invokana. Even if this Court is not inclined to judicially notice the multitude of types and sources of materials supporting J&J's awareness of and participation in the development and marketing of Invokana, this Court should *still* allow claims against J&J to proceed at this stage in the litigation.

Plaintiffs' claims allege that J&J, *inter alia*, marketed Invokana. Compl ¶10. Based on far less, indeed mere knowledge of a subsidiary's wrongdoing, the Northern District of Texas allowed such claims to proceed against J&J with respect to its medical device wholly-owned subsidiary, DePuy. *Lay v. DePuy Orthopaedics, Inc.* (In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.), No. 3:11-MD-2244-K, 2014 WL 3557392 (N.D. Tex. July 18, 2014). There, the court reasoned that Restatement (Second) of Torts §876(b) applies because J&J "is subject to liability for harm to a third person resulting from the tortious conduct of another if [it] knows that the other's [here, Janssen's] conduct constitutes a breach of duty and gives substantial assistance

or encouragement to the other so to conduct himself." *Id.* at *3. The case had already survived on a motion to dismiss on this ground and discovery revealed that the "evidence ... raises fact issues that the Johnson & Johnson Companies knew that DePuy was engaged in the manufacture and marketing of a defective product and that they provided assistance to DePuy in marketing that product." *Id.* That knowledge included, among other things, that its subsidiary was facing manufacturing problems with its hip components, which J&J continued to exercise control over marketing and advertising, that the J&J name was placed on packaging of the device, and that the J&J name was used in doctor marketing efforts. *Id.* at *3.

Both New Jersey and Kentucky recognize the Restatement (Second) of Torts §876(b). "The Supreme Court of New Jersey adopted the Restatement (Second) of Torts § 876(b) standard" *Shah v. Wisconsin*, No. CIV. 11-0419, 2011 WL 5192127, at *5 (D.N.J. Oct. 31, 2011) (citing *Tarr v. Ciasulli*, 181 N.J. 70, 853 A.2d 921, 928 (N.J. 2004)); *see also Failla v. City of Passaic*, 146 F.3d 149, 158 (3d Cir. 1998); *Hurley v. Atlantic City Police Dep't*, 174 F.3d 95, 129 (3d Cir. 1999); *Bondi v. Citigroup, Inc.*, No. L-10902-04, 2005 N.J. Super. Unpub. LEXIS 790, 2005 WL 975856, at *17 (N.J. Super Ct. Law Div. Feb. 28, 2005) (stating that courts in this circuit and in New Jersey recognize "civil aiding and abetting liability" as described in the Restatement (Second) of Torts § 876(b)). *See Miles Farm Supply, LLC v. Helena Chem. Co.*, 595 F.3d 663, 666 (6th Cir. 2010) (Kentucky "recognizes a claim for aiding and abetting tortious conduct, … [a]nd it, like the majority of jurisdictions, follows the Restatement [(Second) of Torts § 876(b)] in defining the claim.").

The facts alleged and/or judicially noticeable here support a claim under the Restatement (Second) of Torts §876(b). As noted above, this Court can take judicial notice of the fact that J&J: 1) directed the physical labeling of Invokana, 2) published media information about Invokana's method of action, 3) announced to its shareholders its hopes for an approval of Invokana in 2012, 4) shared executives between J&J and Janssen, and 5) J&J's consumer brand director was (and remains) in charge of Invokana's marketing. Any one of these facts could lead a reasonable juror to believe that J&J's conduct constitutes a breach of duty and gives substantial assistance or

encouragement to Janssen's conduct.

Moreover, Plaintiffs' design defect does not call for the Defendant's to reformulate Invokana *now*, it is a claim that they should not have submitted the formulation (i.e., its design) in the first instance for approval. In other words, it is incumbent upon the drug manufacturer to make sure the drug is safe at all times – including the time the drug is first brought to market.

D. Mrs. Bowling's Loss-Of-Consortium Claim (Count 13) Survives

Because Mr. Bowling's claims survive, Mrs. Bowling's derivative claims survive.

VI. CONCLUSION

Plaintiffs' complaint meets the applicable pleading standards. As a result, Defendants' motion to dismiss should be denied in its entirety.

Respectfully submitted,
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CERTIFICATE OF SERVICE

It is hereby certified that a true copy of the foregoing was served electronically via the Court's electronic filing system on the 15th day of August 2016, upon all counsel of record.

Dated: August 15, 2016

/s/ Christopher A. Seeger
Christopher A. Seeger